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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/227,854	01/11/1999	JIAN NI	PF210D1	7606

22195 7590 05/26/2004

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EXAMINER	
BRANNOCK, MICHAEL T	

ART UNIT	PAPER NUMBER
1646	

DATE MAILED: 05/26/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/227,854	NI ET AL.	
	Examiner	Art Unit	
	Michael Brannock	1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *27 April 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *35-54* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) *35-54* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Status of Application: Claims and Amendments

Applicant is notified that the amendments put forth on 4/27/04, have been entered in full.

Applicant is notified that the finality of the prior Office action, 4/5/04, has been withdrawn in view of the new issues discussed below.

The indicated allowability of claims 35-54 is withdrawn in view of the reference(s) to Hitomi et al. Rejections based on the newly cited reference(s) follow.

Response to Amendment

Applicant is notified that any outstanding objection or rejection that is not expressly maintained in this Office action has been withdrawn in view of Applicant's amendments.

New Rejection:

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.
>
> (g)(1) during the course of an interference conducted under section 135 or section 291, another inventor involved therein establishes, to the extent permitted in section 104, that before such person's invention thereof the invention was made by such other inventor and not abandoned, suppressed, or concealed, or (2) before such person's invention thereof, the invention was made in this country by another inventor who had not abandoned, suppressed, or concealed it. In determining priority of invention under this subsection, there shall be considered not only the respective dates of conception and reduction to practice of the invention, but also the reasonable

diligence of one who was first to conceive and last to reduce to practice, from a time prior to conception by the other.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claims 35-54 are rejected under 35 U.S.C. 102(e) as being anticipated by U.S. Patent No: 6,313,267, to Hitomi et al., which is a division of US application number 08/568310 filed December 6, 1995. Hitomi et al. claim a polypeptide, SEQ ID NO: 20, (claim 1) having an amino acid sequence 100% identical to the instant SEQ ID NO: 2 as well as heterologous fusions thereof (claim 2). Applicant's Declaration under CRF 1.131, filed 4/17/04 cannot be used to overcome the rejection, see CFR 1.131(a)(1).

CFR § 1.131 Affidavit or declaration of prior invention.

(a) When any claim of an application or a patent under reexamination is rejected, the inventor of the subject matter of the rejected claim, the owner of the patent under reexamination, or the party qualified under §§ 1.42, 1.43, or 1.47, may submit an appropriate oath or declaration to establish invention of the subject matter of the rejected claim prior to the effective date of the reference or activity on which the rejection is based. The effective date of a U.S. patent, U.S. patent application publication, or international application publication under PCT Article 21(2) is the earlier of its publication date or date that it is effective as a reference under 35 U.S.C. 102(e). Prior invention may not be established under this section in any country other than the United States, a NAFTA country, or a

> WTO member country. Prior invention may not be established under this section before December 8, 1993, in a NAFTA country other than the United States, or before January 1, 1996, in a WTO member country other than a NAFTA country. *Prior invention may not be established under this section if either:*
> *(1) The rejection is based upon a U.S. patent or U.S. patent application publication of a pending or patented application to another or others which claims the same patentable invention as defined in § 1.601(n);* or
> (2) The rejection is based upon a statutory bar.
> (b) The showing of facts shall be such, in character and weight, as to establish reduction to practice prior to the effective date of the reference, or conception of the invention prior to the effective date of the reference coupled with due diligence from prior to said date to a subsequent reduction to practice or to the filing of the application. Original exhibits of drawings or records, or photocopies thereof, must accompany and form part of the affidavit or declaration or their absence satisfactorily explained.

Hitomi et al. claims priority under 35 U.S.C. 119(a) to Japanese applications JP 7-45564 and JP-70468, both filed on March 6, 1995. The effective filing date of an application for the purpose of establishing an interference is governed by CFR 1.601(g).

§ 1.601 Scope of rules, definitions.

> This subpart governs the procedure in patent interferences in the Patent and Trademark Office. This subpart shall be construed to secure the just, speedy, and inexpensive determination of every interference. For the meaning of terms in the Federal Rules of Evidence as applied to interferences, see § 1.671(c). Unless otherwise clear from the context, the following definitions apply to this subpart:
>
> (g) The effective filing date of an application is the filing date of an earlier application, benefit of which is accorded to the application under 35 U.S.C. 119, 120, 121, or 365 or, if no benefit is accorded, the filing date of the application. The effective filing date of a patent is the filing date of an earlier application, benefit of which is accorded to the patent under 35 U.S.C. 119, 120, 121, or 365 or, if no benefit is accorded, the filing date of the application which issued as the patent.

Thus the effective filing date of Hitomi et al. for to use as evidence to establish priority of invention is March 6, 1995, whereas the effective filing date of Hitomi et al for use as a reference against Applicant's claims is the US filing date December 6, 1995, see In re Hilmer, 359 F.2d

859, 149 USPQ 480 (CCPA 1966), wherein the court determined "A patent may be "entitled" to a foreign filing date for some purposes and not for others, just as a patent may be "used" in two ways. A patent owner uses his patent as a legal right to exclude others, granted to him under 35 U.S.C. 154. Others, wholly unrelated to the patentee, use a patent, not as a legal right, but simply as evidence of prior invention or prior art, i.e., as a "reference." This is not an exercise of the patent right. This is how the Patent Office is "using" the Habicht patent. These are totally different things, governed by different law, founded on different theories, and developed through different histories."

In the instant case the effective filing date for establishing an interference is governed by CFR 1.601(g), whereas the date to be used as a reference under 35 U.S.C. 102(e) is governed by 35 U.S.C. 102(e).

37 CRF § 1.608 Interference between an application and a patent; prima facie showing by applicant.

(a) When the effective filing date of an application is three months or less after the effective filing date of a patent, before an interference will be declared, either the applicant or the applicant's attorney or agent of record shall file a statement alleging that there is a basis upon which the applicant is entitled to a judgment relative to the patentee.

(b) When the effective filing date of an application is more than three months after the effective filing date of a patent, the applicant, before an interference will be declared, shall file evidence which may consist of patents or printed publications, other documents, and one or more affidavits which demonstrate that applicant is prima facie entitled to a judgment relative to the patentee and an explanation stating with particularity the basis upon which the applicant is prima facie entitled to the judgment. Where the basis upon which an applicant is entitled to judgment relative to a patentee is priority of invention, the evidence shall include affidavits by the applicant, if possible, and one or more corroborating witnesses, supported by documentary evidence, if available, each setting out a factual description of acts and circumstances performed or observed by the affiant, which collectively would prima facie entitle the applicant to judgment on priority with respect to the

effective filing date of the patent. To facilitate preparation of a record (§ 1.653(g)) for final hearing, an applicant should file affidavits on paper which is 21.8 by 27.9 cm. (8 1/2 x 11 inches). The significance of any printed publication or other document which is self-authenticating within the meaning of Rule 902 of the Federal Rules of Evidence or § 1.671(d) and any patent shall be discussed in an affidavit or the explanation. Any printed publication or other document which is not self-authenticating shall be authenticated and discussed with particularity in an affidavit. Upon a showing of good cause, an affidavit may be based on information and belief. If an examiner finds an application to be in condition for declaration of an interference, the examiner will consider the evidence and explanation only to the extent of determining whether a basis upon which the application would be entitled to a judgment relative to the patentee is alleged and, if a basis is alleged, an interference may be declared.
[49 FR 48416, Dec. 12, 1984, added effective Feb. 11, 1985; revised, 60 FR 14488, Mar. 17, 1995, effective Apr. 21, 1995]

Applicant is notified that in order to declare an interference, Applicant must provide a proper showing under CFR § 1.608(b) not CFR § 1.608(a), because the effective filing date of Hitomi et al., as governed by CFR § 1.601(g), is March 6, 1995, which is more than three months from Applicant's effective filing date of December 8, 1995. Although the MPEP 2308.1 is admittedly confusing on this point, the statutes regarding interferences, as set forth CFR § 1.601(g) and CFR § 1.608, are clear.

Conclusion

No claims are allowable

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Brannock, Ph.D., whose telephone number is (571) 272-0869. The examiner can normally be reached on Mondays through Fridays from 10:00 a.m. to 4:00 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz, Ph.D., can be reached at (571) 272-0887.

Official papers filed by fax should be directed to (703) 872-9306. Faxed draft or informal communications with the examiner should be directed to (703) 308-0294.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Elizabeth C. Kemmerer

MB

ELIZABETH KEMMERER
PRIMARY EXAMINER

May 20, 2004